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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,722	06/24/2005	David William Parker	1652-29	9109

23117 7590 01/09/2007  
NIXON & VANDERHYE, PC  
901 NORTH GLEBE ROAD, 11TH FLOOR  
ARLINGTON, VA 22203

EXAMINER
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ANDERSON, MICHAEL J

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/529,722	<b>Applicant(s)</b> PARKER ET AL.	
	<b>Examiner</b> Michael J. Anderson	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/30/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 0222731.2 GB filed on 3/30/2005.

### ***Information Disclosure Statement***

2. The references cited in the Information Disclosure Citation (IDC) have been considered, and will be listed on any patent resulting from this application since they were provided on a separate list in the IDC in compliance with 37 CFR 1.98(a)(1).

### ***Drawings***

3. The drawings are objected to because element # 1.2 is missing the decimal point. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

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of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-4 and 6-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Sullivan (US Patent #5,330,430) (Sullivan).

6. With regard to claim 1, Sullivan discloses a hypodermic syringe comprising: a housing, said housing including a barrel portion and an injectant chamber, the injectant chamber having a smaller cross-sectional area than the barrel portion; a plunger slidably mounted within the barrel portion, comprising a piston which extends into the injectant chamber; a retractable needle assembly; and a stored energy means; configured so that, at the completion of an injection stroke, the piston may become

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attached to the needle assembly and the stored energy in the stored energy means released to retract the needle assembly into the housing (figures 2 and 5).

7. With regard to claim 2, Sullivan discloses as for claim 1 and further discloses wherein the stored energy means is located in the plunger (figures 2 and 5).

8. With regard to claim 3, Sullivan discloses as for claim 1 and further discloses wherein, following needle retraction, residual stored energy is used to retain the needle and plunger within the housing (figure 2 and 5).

9. With regard to claim 4, Sullivan discloses as for claim 1 and further discloses non-reversible snap-fitting formations for securely retaining the needle assembly within the syringe after use (figures 4 and 5).

10. With regard to claim 6, Sullivan discloses as for claim 1 and further discloses wherein the injectant chamber has a capacity of 3 ML or less (figure2).

11. With regard to claim 7, Sullivan discloses a small capacity hypodermic syringe comprising a housing including an injectant chamber of small cross-sectional area, a retractable needle assembly, a stored energy means for effecting retraction and a plunger, wherein the parameters of a stored energy means are not limited by the dimensions of the injectant chamber (figures 2 and 5).

12. With regard to claim 8, Sullivan discloses as for claim 7 and further discloses the stored energy means is a spring (figures 2 and 5).

13. With regard to claim 10, Sullivan discloses as for claim 7 and further discloses wherein the cross-sectional area of the needle assembly is smaller than the cross-

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sectional area of the injectant chamber and the needle assembly comprises a seal (figures 2 and 5).

14. With regard to claim 11, Sullivan discloses as for claim 7 and further discloses wherein, following needle retraction, residual spring energy is used to retain the needle and plunger within the housing (figures 2 and 5).

15. With regard to claim 12, Sullivan discloses as for claim 7 and further discloses non-reversible snap-fitting formations for securely retaining the needle assembly within the syringe after use (figure 5).

16. With regard to claim 13, Sullivan discloses as for claim 1 and further discloses one or more components of the syringe are located and retained by the use of snap-fits during assembly (figures 2 and 5).

17. With regard to claim 15, Sullivan discloses a hypodermic syringe comprising: a housing, said housing including an injectant chamber; a plunger slidably mounted within the housing; a piston mounted on the plunger comprising a first CO-OPERATING feature; a retractable needle assembly comprising a second co-operating feature; and a stored energy means for effecting the retraction of the needle assembly, wherein the first and second CO-OPERATING features are configured to lock together at the completion of an injection stroke, said the co-operating features being arranged so as not to impede the complete evacuation of the injectant chamber (figures 4 and 5).

18. With regard to claim 16, Sullivan discloses as for claim 15 and further discloses wherein the injectant chamber has a capacity equal to or less than 3 ML (figure 2).

***Claim Rejections - 35 USC § 103***

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan in view of Hall (US patent # 5,195,985) (Hall). Sullivan discloses as discussed above in rejection of claim 1. With respect to claim 5 however, Sullivan does not disclose the first part of the needle assembly having a non-circular cross-section. Hall teaches a first part of the needle assembly has a non-circular cross-section. Therefore, it would have been obvious to a person skilled in the art at the time the invention was made to modify Sullivan as taught by Hall (column 22, lines 14-18 and figures 7 and 10) to allow the first part of the needle assembly to have a non-circular cross-section for a safety shield.

21. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan in view of Hall (US patent # 5,195,985) (Hall). Sullivan discloses as discussed above in rejection of claim 7. With respect to claim 9 however, Sullivan does not disclose the needle assembly is mounted in the housing with the needle pre-sheathed. Hall teaches the needle assembly is mounted in the housing with the needle pre-sheathed (figure 2). Therefore, it would have been obvious to a person skilled in the art at the time the invention was made to modify Sullivan as taught by Hall to allow the needle assembly to be mounted in the housing with the needle pre-sheathed for a safety shield.

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22. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan in view of Ris (US patent # 5,171,304) (Ris). Sullivan discloses as discussed above in rejection of claim 1. With respect to claim 9 however, Sullivan does not disclose the plunger closure piece having an aperture. Ris teaches, with prior art, the plunger closure piece having an aperture (figure 3, element #196). Therefore, it would have been obvious to a person skilled in the art at the time the invention was made to modify Sullivan as taught by Ris to allow the plunger closure piece to have an aperture to prevent inward movement.

### ***Double Patenting***

23. Claims 1-16 of this application may conflict with claims 1-12 of Application No. 10/149,756. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

### ***Conclusion***

References considered pertinent to Applicants' disclosure are listed on form PTO-892.

All references listed on form PTO-892 are cited in their entirety.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Anderson whose telephone number is (571) 272-2764. The examiner can normally be reached on M-F 7:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael J Anderson  
Examiner  
Art Unit 3767

MJA  
12/22/2006

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

